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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,248

09/22/2006

Elliott P. Dawson

16306-1US

6225

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7590

04/21/2009

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

04/21/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/599,248	<b>Applicant(s)</b> DAWSON ET AL.	
	<b>Examiner</b> MICHAEL HOBBS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 25-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 June 2008 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :066/12/2007, 08/05/2008, 04/09/2009.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group 1, claims 1-24 in the reply filed on 04/09/2009 is acknowledged. Claims 25-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
2. Claims 1-24 are pending further examination upon the merits.

***Information Disclosure Statement***

3. The information disclosure statement(s) (IDS) submitted on 06/12/2007, 08/05/2008 and 04/09/2009 have been considered by the examiner.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Regarding claim 20, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-5, 9-13, 16, 17, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yokoyama et al. (US 2004/0147854 A1).

9. Yokoyama discloses an instrument for collecting and recovering saliva that for claim 1 includes a water-resistant substrate (substrate 1) or support that has a "top surface, bottom surface and a lateral edge" (Fig. 1). The collection instrument further includes a sample zone (zone 2) that has more than one opening or recess (Fig. 1; [0037]). In order to collect the saliva, Yokoyama includes a hydrophilic absorbent that is made of such materials as cotton or cellulose ([0040]) and is impregnated with a bactericide that includes a stabilizer and the bactericide is being interpreted as being in a "solid state". The sample zone or recesses of Yokoyama stop at the absorbent and to not extend through to the bottom surface (Fig. 1). Finally, while not specifying the composition that includes the bactericide remains in the sample zone, the absorbent of Yokoyama is fully capable of retaining the composition within the sample zone.

10. Regarding claims 2 and 3, the water-resistant material of Yokoyama is being interpreted as being hydrophobic and the material used to construct the substrate is polypropylene ([0041]). For claim 4, the sample zone of Yokoyama includes "recesses"

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that have a circular shape (Fig. 1) and for claims 5 and 6 the sample zone also includes more than two sites (Fig. 1). For claims 9 and 10, the more than one sample zone have different shapes such as a circle or a triangle (Fig. 1) and for claim 11, the composition in the sample zone is being interpreted as being in a solid state as was discussed above. For claim 12, the absorbent is a polymeric material such as nylon ([0040]) which Yokoyama discloses as fiber and therefore, is being interpreted as having a "fibrous form". For claims 12 and 13, the absorbent fiber is hydrophilic and is a single material ([0039]).

11. For claim 14, Yokoyama also discloses an alternative blend of the fiber that includes more than one material ([0040]). Furthermore, for claim 16, the absorbent can be made of cellulose acetate ([0040]) or other materials such as cellulose fiber or cotton. Finally, for claims 22 and 23, the sample zone comprises a depression "when viewed from top" (Fig. 1) and the end of the substrate is fully capable of functioning as a handle.

12. Therefore, Yokoyama meets the limitations of claims 1-6, 9-16, 22 and 23.

### ***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama et al. (US 2004/0147854 A1).

17. With regards to claim 7, Yokoyama does not disclose the number of sample zones ranging between 20 and 200 zones. However, it would be obvious to one of ordinary skill in the art to employ more than one sample zone within Yokoyama in order to obtain the predictable result of collecting a plurality of viable test samples using only one sample collection device. See MPEP 2144.04 VI (B).

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18. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama et al. (US 2004/0147854 A1) in view of Charlton et al. (US 5,989,921).

19. Regarding claim 8, Yokoyama is silent regarding the sample zones having the same shape. Charlton discloses a device for detecting a pre-selected ligand from a sample of body fluid where the device for claim 8 includes a control site (site 16') and a test site (site 18') that are of the same shape. Barring any unexpected results from the outer casing having test sites of the same shape, the choice of shape for the test sites/sample zone is an engineering design choice that would be within the skills of and obvious to the skilled artisan. Therefore, having test sites or sample zones of the same shape would be obvious to one of ordinary skill in the art to employ the sites of Charlton within the substrate of Yokoyama in order to have test sites of the same shape.

20. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama et al. (US 2004/0147854 A1) in view of Fukunishi et al. (US 6,084,005).

21. With regards to claim 17, Yokoyama discloses using cetylpyridinium chloride ([0038]) as the bactericidal ingredient, but is silent regarding the use of the hydrochloride.

22. Fukunishi discloses using cetylpyridinium hydrochloride as a microbiocide within a antimicrobial carrier-detector composition (col. 6 lines 1-3). Furthermore, the uses of both compounds, cetylpyridinium chloride of Yokoyama and cetylpyridinium hydrochloride of Fukunishi, are known within the art and would have been known to one of ordinary skill in the art at the time of the instant application. Therefore, it would have



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been obvious for one of ordinary skill in the art to employ the cetylpyridinium hydrochloride biocide of Fukunishi within the bactericide of Yokoyama in order to obtain the predictable result of sterilizing bacteria that might affect the results of the collected sample.

23. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokoyama et al. (US 2004/0147854 A1) in view of Zhang-Keck and Stallcup (*Journal of Biological Chemistry*, vol. 263, No. 7 pp3514) (will be referred to as Zhang-Keck).

24. Yokoyama is silent regarding the limitations of claims 18-21.

25. Zhang-Keck discloses an assay that includes optimized reaction conditions and specific inhibitors for the initiation of transcription by RNA polymerase that for claims 18-21, that includes using a composition with Vanadyl ribonucleoside complex, Na<sub>2</sub> EDTA, bovine serum albumin and Tris/hydrochloride (page 3514, Experimental procedures) where the vanadyl complex is being interpreted as a vanydyl complex since it appears that both are alternative spellings for the same compound. While Zhang-Keck do not specifically state that the buffer is only Tris, however, Tris is a well known buffer in the art that one of ordinary skill in the art could easily substitute in place of the buffer used by Zhang-Keck. Further, it would be obvious to one of ordinary skill in the art to employ the composition of Zhang-Keck within the device of Yokoyama in order to maintain the viability of the saliva sample obtained by the device. The suggestion for using this composition at the time of the instant application would have been in order to have the

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efficient removal of cyto-plasmic debris in order to prevent severe degradation of the RNA products of the reaction (page 3516, *Effect of Ribonuclease Inhibitors*).

### ***Conclusion***

26. Claims 1-24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/William H. Beisner/  
Primary Examiner, Art Unit 1797

/M. H./  
Examiner, Art Unit 1797